IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED	:	
Plaintiff,	:	Civil Action No. 04-171-KAJ
v.	:	**REDACTED VERSION**
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED	:	
Defendants.	:	

PLAINTIFF GLAXO'S MEMORANDUM IN SUPPORT OF ITS MOTION PURSUANT TO FED. R. CIV. P. 56 FOR SUMMARY JUDGMENT OF PATENT INFRINGEMENT

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Dated: June 30, 2006

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

FEDERAL CASES

TABLE OF AUTHORITIES

FEDERAL STATUTES

I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Glaxo Group Limited ("Glaxo") patented a new and improved aqueous oral syrup formulation of ranitidine, an anti-ulcer medicine sold under the brand name Zantac® Syrup. On or about February 5, 2004, Glaxo received notice that defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (hereafter "defendant" or "Teva") had submitted Abbreviated New Drug Application No. for generic Ranitidine Oral Solution USP, 15mg/mL (Teva's "ANDA Product") to the Food and Drug Administration ("FDA"). Defendant certified to the FDA that its ANDA Product would not infringe Glaxo's U.S. Patent No. 5,068,249 (the " '249 patent") and requested FDA approval prior to the patent's expiration date. Glaxo filed its complaint in this action on March 18, 2004 alleging infringement of the claims (1-12) of the '249 patent. The '249 patent expires on November 26, 2008.

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During the course of discovery, defendant Teva admitted that its ANDA Product contains all of the claim elements of claims 1-12 of Glaxo's '249 patent except for four claim elements that are the subject of this brief. Discovery closed on May 26, 2006, with expert depositions concluding on June 8, 2006. Given the admissions by defendant's fact and expert witnesses and the uncontradicted infringement analysis of Glaxo's expert, Professor Bradley D. Anderson, Glaxo submits this memorandum in support of its Motion Pursuant to Fed. R. Civ. P. 56 for Summary Judgment of Patent Infringement By Defendants Teva Pharmaceuticals. This motion is supported by the Declarations of Oren D. Langer[1] and Bradley D. Anderson.[2]

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[1] "Langer Decl." refers to the "Declaration of Oren D. Langer, in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief and Summary Judgment Motions on U.S. Patent No. 5,068,249" submitted herewith.

[2] "Anderson Decl." refers to the "Declaration of Bradley D. Anderson, Ph.D. in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief on U.S. Patent No. 5,068,249" submitted herewith.

II. SUMMARY OF ARGUMENT

The inventor of the '249 patent, Dr. David Long, unexpectedly discovered the benefit of adding ethanol to Glaxo's Zantac® Syrup formulation in order to enhance the stability of ranitidine and prolong the shelf-life of Zantac® Syrup, an anti-ulcer medication. The enhanced ranitidine stability provided by this valuable invention allowed Glaxo to extend the FDA-approved shelf-life of Zantac® Syrup from 18 months to 24 months, a benefit of great commercial importance acknowledged by defendant.

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The uncontroverted admissions and expert evidence are further bolstered by the decision in *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998). In *Pharmadyne*, the court held that a very similar aqueous oral ranitidine formulation containing 12.5% propylene glycol infringed the '249 patent under the doctrine of equivalents. The court found that: "It is apparent that propylene glycol in the accused product is the functional equivalent of ethanol in the '249 patent." *Id.* at 288.

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[4] "Anderson Opening Rpt." refers to "Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Expert Witness Report Concerning The Issue of Infringement of Glaxo's '249 Patent" attached as Exhibit A to the Anderson Decl.

[5]

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The mountain of infringement evidence only grows higher when the Court considers litigation conduct by defendant that justifies a negative inference of patent infringement.

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Plaintiff Glaxo respectfully requests that the Court enter summary judgment that defendant's ANDA Product infringes claims 1-12 of the '249 patent under the doctrine of equivalents. Fed. R. Civ. P. 56.

III. STATEMENT OF FACTS

A. Glaxo's '249 Patented Invention

1. The Surprising Benefit Of The Invention

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Glaxo enjoys market exclusivity for its Zantac® Syrup anti-ulcer medicine until November 26, 2008 because of the protection afforded by the '249 patent.[7] The United States Patent and Trademark Office ("PTO") granted the '249 patent because a Glaxo researcher, Dr. David Long, unexpectedly discovered the benefit of adding ethanol to an aqueous formulation of ranitidine for oral administration to enhance the stability of ranitidine and prolong the shelf-life

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[7] Pediatric exclusivity extends until May 26, 2009.

of the drug product. This unexpected discovery of enhanced ranitidine stability, imparted by adding ethanol to an aqueous formulation of ranitidine for oral administration, was supported by Glaxo's extensive stability studies on Zantac® Syrup formulations with and without ethanol.[8]

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The invention of the '249 patent is centered on using ethanol as a stabilizer to enhance the stability of ranitidine in an aqueous formulation for oral administration. Glaxo's expert, Professor Anderson, **REDACTED** agree that as of the December 12, 1986 foreign priority date for the '249 patent the use of ethanol to enhance ranitidine stability in an aqueous formulation for oral administration would have been surprising to one of ordinary skill in the art. (Anderson Rebuttal Rpt.[9] ¶¶ 28, 34;

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[8] Glaxo respectfully refers the Court to the detailed explanation of the relevant technology and background of the invention contained in Plaintiff Glaxo Group Limited's Opening Claim Construction Brief Construing The Disputed Claim Terms Of Glaxo's U.S. Patent No. 5,068,249 at pp.4-7, which will not be repeated here.

[9] "Anderson Rebuttal Rpt." refers to the Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Rebuttal Expert Witness Report attached as Exhibit B to the Anderson Decl.

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2. The '249 Patent Specification

The '249 patent is entitled "Aqueous Ranitidine Compositions Stabilized with Ethanol." (Langer Decl., Ex. 1, cover page). The PTO issued the '249 patent on November 26, 1991 from U.S. Application No. 494,804. (*Id.*).[10] The invention of the '249 patent "relates to a pharmaceutical composition containing as active ingredient the histamine H_2 antagonist ranitidine." (*Id.* at Col. 1:9-11). The '249 patent first describes Glaxo's own prior art patents disclosing aqueous ranitidine solutions (injection solutions and oral solutions), where shelf-life was improved by adjusting the pH from a pH of 5 to a pH within the range of 6.5-7.5. (*Id.* at Col. 1:12-38).

The '249 patent then characterizes the invention as follows:

> We have now surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of ethanol to the formulation.

[10] U.S. Application No. 494,804 was filed on March 14, 1990 and is a file wrapper continuation of U.S. Application No. 344,620. (Langer Decl., Ex. 1, cover page). U.S. Application No. 344,620 was filed on April 28, 1989 and is a continuation of U.S. Application No. 131,442, which was filed on December 11, 1987. (*Id.*).

> Thus the present invention provides a pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof also containing ethanol. The aqueous formulation is prepared using ingredients of a purity such that it is suitable for administration to patients and will in general contain at least one conventional pharmaceutical excipient in addition to the ethanol and ranitidine and/or physiologically acceptable salts thereof.
>
> The amount of ethanol present in the formulation is such that the resulting formulation has the enhanced stability. Preferably the amount of ethanol in the composition on a weight/volume basis of the complete formulation, is within the range 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v.

(*Id.* at Col. 1:40-60; see also Col. 2:30-34).

The '249 patent specification concludes with an "illustrative example" of a formulation according to the invention. This illustrative example includes 1.68% (w/v) ranitidine hydrochloride as the active ingredient, 7.5% (w/v) of the stabilizing agent ethanol, orthophosphate buffers to control pH, a viscosity enhancing agent (hydroxypropyl methylcellulose), antimicrobial preservative, sweetening agents, flavour, and purified water to 100 ml. (*Id.* at Col. 2:47-65).

3. The '249 Patent Claims

Glaxo's '249 patent contains twelve (12) claims, two of which are independent claims. Independent claims 1 and 11 claim:

> 1. A pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiological acceptable salts thereof, said formulation comprising *a stabilizing effective amount of ethanol* and said composition having a pH in the range of 6.5 to 7.5.
>
> 11. A pharmaceutical composition which is an aqueous formulation of ranitidine suitable for oral administration containing 150 mg ranitidine per 10 ml dose expressed as a free base, said formulation having a pH in the range of 7.0 to 7.3 and also

> containing *7% to 8% weight/volume ethanol* based on the complete formulation.

(Langer Decl., Ex. 1, Col. 2:67 - Col. 3:4 and Col. 4:10-16) (italics added). Representative claims 2 and 3 of the '249 patent are dependent on claim 1 and claim:

> 2. A pharmaceutical composition according to claim 1 containing *2.5% to 10% weight/volume ethanol* based on the complete formulation.
>
> 3. A pharmaceutical composition according to claim 1 containing *7% to 8% weight/volume ethanol* based on the complete formulation.

(*Id.* at Col. 3:5-10)[11] (italics added).

B. Glaxo's Stability Studies Demonstrate the Unexpected Benefit of Adding Ethanol to Enhance Ranitidine Stability In An Aqueous Formulation for Oral Administration

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[11] For a detailed discussion of Glaxo's proposed claim construction, including a discussion of the prosecution history of the '249 patent, Glaxo respectfully refers the Court to Plaintiff Glaxo Group Limited's Opening Claim Construction Brief Construing The Disputed Claim Terms of Glaxo's U.S. Patent No. 5,068,249 starting at p. 15.

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The FDA requires all applicants to perform stability testing of proposed drug products, and the FDA provides standard industry guidance requiring that calculations of shelf-life from stability study data be based on the lower 95% confidence limit of the t_{95} value rather than the t_{95} value itself. (Anderson Opening Rpt. ¶ 46; FDA Guidance at G0035954-959, Langer Decl. Ex. 18).

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It is important to be conservative in the calculation of shelf-life because one wants to be sure that patients receive the label claim dosage of the active ingredient without receiving unnecessary amounts of degradation impurities '249 File History at G000176, G00143-44, Langer Decl., Ex. 10). Professor Anderson, therefore, used the FDA guidance to define shelf-life as the lower 95% confidence limit of t_{95} for each of the ethanol and non-ethanol aqueous oral formulations of ranitidine. (Anderson Opening Rpt. ¶ 46).

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ARGUMENT

IV. STATEMENT OF LAW

A. The Law of Patent Infringement

A determination of infringement requires a two-step analysis. First, the claim must be properly construed to determine its scope and meaning.[16] Second, the claim as properly construed must be compared to the accused device or process. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996); *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1381 (Fed. Cir. 2005) (citation omitted). Claim construction is an issue of law. *Markman*, 52 F.3d at 970-71. Infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Terlep*, 418 F.3d at 1382. For a plaintiff to prove infringement it must show the presence of every element or its substantial equivalent in the accused product by a preponderance of the evidence. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997); *Seal-Flex, Inc. v. Athletic Track and Court Construction*, 172 F.3d 836, 842 (Fed. Cir. 1999).

Infringement is not limited to literal correspondence between the claim and the accused product. If it were, the protection afforded by "the patent grant would be a hollow and useless thing." *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989) (citation omitted). Infringement by equivalents exists if the accused product includes a feature

[16] Plaintiff Glaxo refers the Court to its Opening Claim Construction Brief Construing The Disputed Claim Terms of Glaxo's U.S. Patent No. 5,068,249 for Glaxo's claim construction analysis.

equivalent to a recited claim element. *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950). Infringement by equivalents exists to protect against "an infringer who appropriates the invention but avoids the literal language of the claims." *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1579 (Fed. Cir. 1984); *see also Graver Tank*, 339 U.S. at 608 (infringement jeopardy exists against one who steals the art of an invention but avoids literal infringement by making a non-critical change).

There is no mandatory test for the application of equivalents. The most common expression, however, is that equivalence is made out if the infringing product accomplishes substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed invention. *Warner-Jenkinson*, 520 U.S. at 40; *Graver Tank*, 339 U.S. at 608. Framed another way, an element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial to one of ordinary skill in the art." *Warner-Jenkinson*, 520 U.S. at 40. Evidence of copying is also highly relevant to the question of infringement under the doctrine of equivalents. *See Hilton-Davis Chemical Co. v. Warner-Jenkinson Co. Inc.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995). "[C]opying suggests that the differences between the claimed and accused products or processes – measured objectively – are insubstantial. When an attempt to copy occurs, the fact-finder may infer that the copyist, presumably one of some skill in the art, has made a fair copy with only insubstantial changes." *Id.*

B. The Legal Standard For Summary Judgment

Summary judgment is appropriate and should be granted if there are no disputed issues of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10

(1986); *Stryker Corp. v. Davol, Inc.*, 234 F.3d 1252, 1257 (Fed. Cir. 2000). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248. Glaxo submits that there is no evidence on which defendant can rely to create a genuine dispute of material fact in this motion for summary judgment of patent infringement.

V. DEFENDANT'S ANDA PRODUCT INFRINGES THE CLAIMS OF THE '249 PATENT

A. The Undisputed Evidence Establishes Defendant's Infringement By More Than The Required Preponderance

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Defendant has admitted that its generic version of Zantac® Syrup "contains all the elements of Claims 1 through 11 of U.S. Patent 5,068,249 except for the following: (1) 'a stabilizing effective amount of ethanol' in Claims 1 through 10; (2) '2.5 percent to 10 percent weight/volume ethanol' in Claim 2; (3) '7 percent to 8 percent weight/volume ethanol' in Claims 3, 11 and 12." (6/30/05 Court Conf., D.I. 57 at p. 5).

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C. The *Pharmadyne* Decision, , Is Persuasive Precedent Adding To The Evidence of Defendant's Patent Infringement

1. The *Pharmadyne* Court Found Propylene Glycol to be the Functional Equivalent of Ethanol

In *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998), the court (Davis, J.) opined on the same issue of equivalents raised in this action against defendant. The court in *Pharmadyne* addressed infringement under the doctrine of equivalents based on Pharmadyne's use of 12.5% (w/v) propylene glycol in place of ethanol in its proposed ANDA product. The court, relying on the trial testimony of Glaxo's inventor, Dr. Long, first found that it was "surprising to discover that the addition of ethanol also increased the stability of the ranitidine hydrochloride in the syrup formulation without requiring a change in the preferred pH of 6.5-7.5 of the base formula." *Id.* at 277. The court then noted that "the accused product does not literally infringe the '249 patent because the accused product does not contain the identical alcohol – ethanol. Instead, the accused product contains propylene glycol, a substance that is both an alcohol and a polyol." *Id.* at 283. The court, citing the Supreme Court's decision in

Graver Tank,[19] stated that "the primary issue that must be addressed is whether the propylene glycol in the accused product performs the same function in the same way to obtain the same result as the 7.5% ethanol in the '249 patent." *Id.* at 284.

The court held that "Glaxo met its burden of establishing that the propylene glycol in the accused product performs the same work in substantially the same way and accomplishes the same result as the ethanol in Glaxo's '249 patent." *Pharmadyne*, 32 F. Supp. 2d at 289. In a two-step infringement analysis the court first construed the claims and then compared the accused product to the construed claims. The court found that "there [was] no dispute as to the construction of the claims of the '249 patent" and that "the critical dispute revolves around whether Pharmadyne's use of propylene glycol in the accused product is a mere substitution of the stabilizing ingredient, ethanol, in Claim 1...." *Id.* Despite Pharmadyne's position that "the sole function of propylene glycol in the accused product is to act as a solvent for the paraben preservative system," the Court found that "Glaxo presented substantial, credible evidence that propylene glycol stabilizes ranitidine in the accused product as does ethanol in the '249 patent and that the accused product is not insubstantially different from, nor an improvement over the '249 patent." *Id.* at 291.

The evidence that the court found most compelling was provided by Glaxo's expert, Dr. Paul Wray.[20] Dr. Wray's trial testimony demonstrated that "propylene glycol functions to stabilize ranitidine hydrochloride in the accused product in a manner similar to ethanol stabilizing the compound in the '249 patent." *Pharmadyne*, 32 F. Supp. 2d at 285. The Court found that "Pharmadyne was aware that propylene glycol could be substituted for ethanol and

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19 *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950).

20 Dr. Wray is now deceased.

that Pharmadyne developed the accused product by copying the '249 patent." *Id.* at 288. The court also found that "Glaxo presented highly persuasive evidence demonstrating that propylene glycol in the accused product is the functional equivalent of ethanol in the '249 patent." *Id.* at. 287. Dr. Wray's analysis[21] and the court's finding of infringement with respect to Pharmadyne's use of 12.5% (w/v) propylene glycol

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[21] The *Pharmadyne* court also credited the testimony of Glaxo's other expert witness, Professor Joel Bernstein. The court specifically noted that "Professor Bernstein testified that chemists characterize organic compounds such as alcohols by the functional group they contain.... In the case of alcohols, the functional group is the hydroxyl group.... [and] that organic compounds in the same functional group are formed in the same way, react in the same way, and have the same properties." *Pharmadyne*, 32 F. Supp. 2d at 288. The court concluded by holding that "[t]he stability data and testimony of Drs. Wray and Bernstein, taken as a whole, overwhelmingly support a finding that the propylene glycol in the accused product performs the same function as ethanol in the '249 patent. It is apparent that propylene glycol in the accused product is the functional equivalent of ethanol in the '249 patent." *Id.*

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Defendant has an affirmative obligation to preserve evidence which may be relevant to the issues in the lawsuit once litigation is pending or reasonably anticipated. *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 430 (S.D.N.Y. 2004); *Mosel Vitelic Corp. v. Micron Technology, Inc.*, 162 F. Supp.2d 307, 310-311 (D. Del. 2000); *In re Wechsler*, 121 F. Supp. 2d 404, 415 (D. Del. 2000).

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3. The Circumstances are More than Sufficient to Warrant an Adverse Inference of Patent Infringement

"Where the nature of the alleged breach of a discovery obligation is the non-production of evidence, the court has broad discretion in fashioning an appropriate sanction" and can permit an adverse inference to be drawn from such non-production. *Liafail, Inc. v. Learning 2000, Inc.*,

Civ. Nos. 01-599 and 01-678, 2002 U.S. Dist. Lexis 24803, * 9 (D. Del. December 23, 2002) (attached as Exhibit A) (*citing Residential Funding Corp. v. DeGeorge Financial Corp.*, 306 F.3d 99, 107 (2d Cir. 2002)); *Zubulake*, 229 F.R.D. at 430; *Mosel*, 162 F. Supp. 2d at 311. Rule 37 of the Federal Rules of Civil Procedure provides, in relevant part, that if a party fails to obey a discovery order, the court "may make such orders in regard to the failure as are just...." Fed. R. Civ. P. 37(b)(2). "Even in the absence of a discovery order, a court may impose sanctions on a party for misconduct in discovery under its inherent power to manage its own affairs." *Residential Funding*, 306 F.3d at 107-108.

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"In exercising its discretion, the court may impose an adverse inference instruction where: (1) the party having control over the evidence had an obligation to timely produce it; (2) the party had a 'culpable state of mind;' and (3) the missing evidence is 'relevant' such that a reasonable trier of fact could find that it would support the other party's claim or defense." *Liafail*, 2002 U.S. Dist. Lexis 24803, * 9 (*citing Residential Funding*, 306 F.3d at 107). Factor (1) has been met by defendant's failure to produce the despite repeated requests throughout the case and a Court order. Factor (2) is satisfied because a party can be found to have a culpable state of mind even when it acted only "negligently." *Residential Funding*, 306 F.3d at 108. Defendant has failed to produce the either through intentional lack of effort or, at a minimum, negligence in its destruction. Factor (3) has been aptly demonstrated above.

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Defendant repeatedly demonstrated its indifference to its obligation to produce documents in a timely fashion. For example, during an October 7, 2005 teleconference, Teva's

counsel, on questioning by this Court as to whether Teva had any more "development documents," responded: "[w]e have nothing else to give." (D.I. 71 at p. 15). Remarkably, documents that apparently were not there to be given on October 7, 2005 showed up at the offices of Glaxo's counsel just two days prior to the December 8, 2005 deposition of Mr. Mazumder. (12/6/05 Letter from Teva's Counsel, Langer Decl., Ex. 23). The box contained almost 2000 pages of production documents relevant to this witness's deposition, but the REDACTED was not among them. These documents should have been produced in response to Glaxo's first request for documents which had been served in September 2004 – over one year before the documents were produced. REDACTED

Defendant's excuse that it cannot find the is just that, an excuse. It is apparent that defendant has either purposefully not looked for the , or, as a result of negligence, destroyed it. Glaxo respectfully submits that the sanction of an adverse inference on the issue of patent infringement is appropriate because defendant "should bear the risk of its own negligence." *Residential Funding*, 306 F.3d at 108.

VI. CONCLUSION

For the reasons stated above, Glaxo respectfully requests that the Court find that defendant's accused ANDA Product infringes claims 1-12 of Glaxo's '249 patent under the doctrine of equivalents.

Dated: June 30, 2006

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EXHIBIT A

LEXSEE

LIAFAIL, INC., Plaintiff and Counterclaim Defendant v. LEARNING 2000, INC., JAMES RICHARD STORY, III, individually, ANTONIO SANTINI, individually, ILC, INC., SFD, INC., and S & S ENTERPRISES, Defendants and Counterclaim Plaintiffs and Third-Party Plaintiffs, v. FRANK STUCKI, Third-Party Defendant.

CONSOLIDATED C.A. No. 01-599 GMS and C.A. No. 01-678 GMS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2002 U.S. Dist. LEXIS 24803

December 23, 2002, Decided

SUBSEQUENT HISTORY: Motion granted by, in part, Motion denied by, in part Liafail, Inc. v. Learning 2000, Inc., 2003 U.S. Dist. LEXIS 3545 (D. Del., Mar. 3, 2003)

PRIOR HISTORY: Liafail, Inc. v. Learning 2000, Inc., 2002 U.S. Dist. LEXIS 22620 (D. Del., Nov. 25, 2002)

DISPOSITION: [*1] L2K's Motion for Relief from Spoliation of Evidence GRANTED. L2K's requests for costs as a result of Liafail's alleged misconduct DENIED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff company sued defendant corporation, alleging various contractual theories of liability. The corporation counterclaimed for, inter alia, violation of 15 U.S.C.S. § § 1125(a) and 1125(d). The corporation moved for relief from spoliation of evidence.

OVERVIEW: In response to the corporation's discovery request, the company gave conflicting accounts as to whether evidence contained in two laptop computers had been inadvertently destroyed or had already been provided to the corporation. Because it was unclear what information had been produced and what was still to be produced, the court declined to immediately sanction the company for discovery misconduct. Instead, the company was ordered to correct or clarify the discovery record by producing the requested documents which it had claimed were available or by producing the Bates Numbers of documents which it claimed it had already produced. If the company failed to comply with the court's order, the court indicated that it would order sanctions in the form of an adverse inference jury instruction.

OUTCOME: The motion for relief from spoliation of evidence was granted and the company was ordered to produce all relevant documents from the laptop computers within 30 days.

CORE TERMS: laptop, discovery, marketing, destroyed, e-mail, relevant information, deposition, discoverable, relevance, prong, adverse inference, promoting, disposed, reasonable trier of fact, sales manager, day-to-day, missing, infer, spoliation of evidence, jury instruction, demonstration, questionable, destruction, transferred, responsive, confirmed, forwarded, producing, searched, confirm

LexisNexis(R) Headnotes

Civil Procedure > Discovery > Misconduct

[HN1] Where the nature of the alleged breach of a discovery obligation is the non-production of evidence, the court has broad discretion in fashioning an appropriate sanction. In exercising its discretion, the court may impose an adverse inference instruction where: (1) the party having control over the evidence had an obligation to timely produce it; (2) the party had a culpable state of mind; and (3) the missing evidence is relevant such that a reasonable trier of fact could find that it would support the other party's claim or defense.

COUNSEL: For Liafail Inc, PLAINTIFF: Michael P Kelly, A Richard Winchester, McCarter & English, Wilmington, DE USA.

For Learning 2000 Inc, PLAINTIFF: Martina Bernstein, Sean K Hornbeck, Hornbeck & Associates, Hockessin, DE USA.

For Learning 2000 Inc, James Richard Story, III, Antonio Santini, ILC Inc, SFD Inc, S & S Enterprises, DEFENDANTS: Martina Bernstein, Sean K Hornbeck, Hornbeck & Associates, Hockessin, DE USA.

For Liafail Inc, Frank Stucki, Robert E Stucki, DEFENDANTS: Michael P Kelly, A Richard Winchester, McCarter & English, Wilmington, DE USA.

For Learning 2000 Inc, James Richard Story, III, Antonio Santini, ILC Inc, SFD Inc, S & S Enterprises, THIRD-PARTY PLAINTIFFS: Sean K Hornbeck, Hornbeck & Associates, Hockessin, DE USA.

For Learning 2000 Inc, James Richard Story, III, Antonio Santini, ILC Inc, SFD Inc, S & S Enterprises, COUNTER-CLAIMANTS: Sean K Hornbeck, Hornbeck & Associates, Hockessin, DE USA.

For Liafail Inc, COUNTER-DEFENDANT: Michael P Kelly, A Richard Winchester, McCarter & English, Wilmington, [*2] DE USA.

JUDGES: Gregory M. Sleet, UNITED STATES DISTRICT JUDGE.

OPINIONBY: Gregory M. Sleet

OPINION:

MEMORANDUM AND ORDER

I. INTRODUCTION

On June 5, 2001, the plaintiff and counter-claim defendant, Liafail, Inc. ("Liafail") filed a complaint in the United States District Court for the Western District of Kentucky, setting forth various contractual theories of liability. The United States District Court for the Western District of Kentucky transferred this case to the United States District Court for the District of Delaware on August 29, 2001. This case became Civil Action Number 01-599-GMS.

On October 9, 2001, Learning 2000, Inc ("L2K") commenced Civil Action Number 01-678-GMS in the United States District Court for the District of Delaware. In that complaint, L2K alleges that Liafail violated, *inter alia,* Section 43 of the Lanham Act, 15 U.S.C. § 1125(a); Section 2532 of the Delaware Uniform Deceptive Trade Practices Act, and the Anti-Cybersquatting Consumer Protection Act, 15 U.S.C. § 1125(d).

By stipulation of the parties, the court consolidated Civil Actions 01-599-GMS and 01-678-GMS on November 2, 2001.

Presently before [*3] the court is L2K's motion for relief from spoliation of evidence. For the following reasons, the court will grant this motion in part.

II. BACKGROUND

On October 30, 2001, pursuant to Federal Rule of Civil Procedure 26(a)(1), Liafail identified its national sales manager, Steve Sborov ("Sborov") as "likely to have discoverable information concerning the writings at issue in Liafail's complaint and/ or Liafail's claims, contentions or defenses relating thereto; including, but not limited to, discoverable information concerning the day-to-day operations of Learning 2000; and Learning 2000's complaint against Liafail and its principals and/ or Learning 2000's claims relating thereto."

On November 2, 2001, L2K and Liafail stipulated that "they will preserve all documents, data compilations and tangible things that are in their possession, custody or control, which are relevant or could lead to the discovery of relevant information concerning each party's claims in the above-captioned lawsuit." On November 20, 2001, L2K served requests for production of documents directed to Liafail. The requests sought, among other things:

> (1) all documents concerning Liafail's marketing, [*4] sale, or distribution of the Lifetime Library;
>
> (2) all documents concerning any marketing and sales materials provided by Liafail or representatives involved in the sale or marketing of the Lifetime Library or Learning 2000 Lifetime Library;
>
> (3) all documents concerning all work product produced by Liafail's representatives engaged in the marketing, sale, and distribution of the Lifetime Library; and
>
> (4) all demonstration, sales, and marketing materials for the Lifetime Library used and/ or created by Liafail, its agents, employees or representatives.

The requests further asked Liafail to identify and describe "any document requested herein [that] was formerly in your possession, custody or control and has been lost or destroyed or otherwise disposed of ...."

In response to these requests, Sborov gave Liafail the L2K-issued laptop that he had been using while gaining knowledge of the day-to-day operations of L2K, both as its sales representative and as its national sales manager. Upon receiving the laptop, L2K alleges that Liafail's Vice-President, Keith Hanson ("Hanson")

purged all the files from the computer. L2K further alleges that Liafail made no effort to preserve the [*5] Sborov files by copying them onto another hard drive, disk or other medium before their destruction.

L2K was able to reconstruct some, but not all, of the Sborov files. L2K maintains that, as far as can be ascertained, virtually all of the Sborov Files were relevant to the issues in this litigation. Indeed, L2K argues that, not only were they relevant, the documents were highly incriminating. For example, according to L2K, the documents included an e-mail received by Sborov, and forwarded to Stucki, which established that, in July 2001, Laifail sales representatives were promoting the Lifetime Library by using L2K marketing materials. L2K also points to an e-mail which it claims establishes that, two months later, Liafail sales representatives were still promoting the Lifetime Library by using a demonstration CD that had "Learning 2000 [] splashed all over" it. The e-mail also implicated Stucki's knowledge of these actions. L2K maintains that, to date, Liafail has denied that the conduct evidenced by these e-mails occurred. Alternatively, Liafail denies that it had any notice that its sales representatives engaged in the conduct described in these e-mails.

One week before the close [*6] of discovery, L2K alleges that it discovered additional spoliation during Frank Stucki's ("Stucki") deposition. At his deposition, Stucki testified that he "trashed two laptops in the last seven months." Specifically, he testified that he dropped the first laptop when he was staying at somebody's house in Arizona. The second laptop "slipped out of [his] hands" at home. During his deposition, he maintained that the information on both laptops was destroyed.

With respect to the first laptop ("the 1700 laptop"), Stucki initially testified that "there was nothing on there that-regarding this litigation ...." Later, he contradicted his claim of irrelevance by testifying that whatever was on that laptop was made available to litigation counsel before he disposed of it. L2K now maintains that Liafail's counsel has not confirmed that the files from the 1700 laptop were in fact searched and produced. Nor has it clarified whether (1) it made an independent judgment as to whether the documents on the 1700 laptop were responsive, or (2) whether it simply relied on Stucki's layperson's view of what he believed to be discoverable.

With respect to the second laptop ("the 1720 laptop"), Stucki [*7] was unable to confirm that everything on that laptop was made available to his counsel before it was destroyed. Liafail's counsel itself refused to confirm whether it had, in fact, searched the files on the laptop and whether responsive documents were produced or identified on a privilege log.

In response, Liafail now contends that L2K "already has in its possession the documents at issue in the instant motion." Specifically, Liafail has submitted affidavits to the effect that all of the relevant information was removed from the laptop computers, saved, and then made available to L2K.

III. DISCUSSION

A. The Disputed Files

L2K contends that, in the past, Liafail has maintained that the information L2K now seeks was inadvertently destroyed and is no longer available for production. In response to the present motion, however, Liafail has brought forth affidavits, albeit of questionable validity given its previous assurances that the information no longer exists, that the information does indeed exist and is available for production. *See* Liafail's Answer Brief at 4-5. Liafail even goes so far as to indicate, without any citations to record evidence to support its claims, [*8] that the files "where relevant and appropriate" have been produced to L2K. *See id.* at 2-4 (stating that all relevant information from the Sborov laptop had been produced and that backup files of this information exist). Liafail's current position on the whereabouts of the discovery sought indicates that Liafail may have engaged in questionable discovery tactics. Nevertheless, because on the record before the court, it is unclear what has been produced, and what must still be produced, the court will not immediately sanction Liafail. Rather, it will first afford Liafail the opportunity to correct or clarify the discovery record by producing the requested documents which it has claimed are available, or by producing the Bates Numbers of documents which it claims it has already produced. n1

n1 This order includes the production of all relevant documents within the meaning of Federal Rule of Evidence 401, including those which Liafail has conceded it did not produce due to "marginal relevance." *See* Liafail's Answer Brief at 7, n.6. The order further includes information which Liafail believes L2K already has in its possession due to its own computer file restoration efforts. *See e.g.* *Land Ocean Logistics, Inc. v. Aqua Gulf Corp.*, 181 F.R.D. 229, 240 (W.D.N.Y. 1998) (holding that the defendants "must produce requested documents ... regardless of whether Plaintiff is also in possession of the documents.").

[*9]

B. Sanctions

For the following reasons, should Liafail chose not to heed the court's order and produce the documents of which it claims to have possession, the court will order sanctions against it in the form of an adverse inference jury instruction.

[HN1] Where the nature of the alleged breach of a discovery obligation is the non-production of evidence, the court has broad discretion in fashioning an appropriate sanction. *See* Residential Funding Corp. v. Degeorge Fin. Corp., 306 F.3d 99, 107 (2d Cir. 2002). In exercising its discretion, the court may impose an adverse inference instruction where: (1) the party having control over the evidence had an obligation to timely produce it; (2) the party had a "culpable state of mind;" and (3) the missing evidence is "relevant" such that a reasonable trier of fact could find that it would support the other party's claim or defense. *See id.* Liafail has not argued that the discovery at issue was, or is, out of its control, nor that it did not have an obligation to timely produce it. Thus, the court concludes that the first prong of the test has been met. It will now address the remaining two prongs.

With regard to the [*10] culpability prong, the court finds that, should Liafail disregard this order, it will have acted in bad faith. Specifically, if Liafail does not produce the requested files, it will then be in the position of having intentionally misrepresented the availability of the evidence before the court on this motion.

Further informing the court's decision on this point are the clear discrepancies in Liafail's two versions of the events, which tend to demonstrate bad faith on its part. For example, in his present affidavit, Stucki testified that attempts were made to save the contents of the 1700 laptop, and that, indeed, the contents were saved. *See* Stucki Affidavit at P 4. During his earlier deposition, however, Stucki testified that the contents of the 1700 laptop were "destroyed," and that no attempts were made to retrieve the documents from that laptop. *See* Stucki Deposition at 1366.

Additionally, Stucki's affidavit claims that the entire contents of the 1720 laptop were transferred to the old 1700 laptop and that "the transfer was successful and ... no documents or filed were omitted from the transfer and none were deleted." Stucki Affidavit at P 6. Stucki further states in [*11] his affidavit that, "I have reviewed the contents of the 1700 laptop I now use and have confirmed that all potentially relevant information which was contained on it ... has been made available to my counsel." *Id.* at P 8. The court finds it difficult to reconcile this statement with Liafail's counsel's earlier representation that both laptops were discarded because they could not be repaired. *See* June 20, 2002 Letter from W. Bruce Baird to Sean K. Hornbeck (stating that the Stucki computers "were not repairable [and] they were disposed of long ago.").

Finally, the court is satisfied that the requested discovery documents are relevant, such that a "reasonable trier of fact could infer that 'the destroyed [or unavailable] evidence would have been of the nature alleged by the party affected by its destruction.'" Residential Funding Corp., 306 F.3d at 109. Liafail has put Stucki's scienter at issue in this litigation by denying that he had knowledge of certain events. Accordingly, the identity of the documents he had stored on his laptops may be probabtive of what he knew or should have known.

With regard to the relevance of the Sborov files, L2K has represented [*12] that, based on the information it was able to salvage, the files were relevant to the issues in this litigation. By way of example, L2K has provided an e-mail received by Sborov, and forwarded by Stucki, which allegedly establishes that, in July 2001, Liafail sales representatives were promoting the Lifetime Library by using L2K marketing materials. *See* Liafail's Opening Brief, Ex. K.

Additionally, the court notes that a jury would be permitted to infer that Liafail's bad faith alone is sufficient circumstantial evidence from which a reasonable fact finder could conclude that the missing evidence was unfavorable to that party. *See* Residential Funding Corp., 306 F.3d at 109. Accordingly, the court finds that the requisite relevance factor has been satisfied.

IV. CONCLUSION

Thus, while it would be entirely appropriate for the court to sanction Liafail immediately based on the conflicting stories Liafail has espoused in an apparent attempt to perform an end-run around both L2K's discovery requests and the current motion, the court nevertheless concludes that the more just route is to allow Liafail to correct its apparent wrongs before imposing sanctions. [*13] n2

n2 In light of counsel's joint request for additional time to respond to the motions in limine, and the need to move the trial to a later date as a result of this request, the court finds this solution to be imminently fair to both parties.

For the aforementioned reasons, IT IS HEREBY ORDERED that:

1. L2K's Motion for Relief from Spoliation of Evidence (D.I. 260) is GRANTED as follows:

2. Liafail shall produce any and all relevant documents, files, or the like, originating from the Sborov laptop, as well as the 1700 and 1720 laptops, within thirty (30) days of the date of this order.

3. Should Liafail not comply with this order, the court will order sanctions against it in the form of an adverse inference jury instruction.

4. L2K's requests for costs as a result of Liafail's alleged misconduct is DENIED at this time.

Gregory M. Sleet

UNITED STATES DISTRICT JUDGE

Dated: December 23, 2002

CERTIFICATE OF SERVICE

I hereby certify that on June 30 2006, I electronically filed **PLAINTIFF GLAXO'S MEMORANDUM IN SUPPORT OF ITS MOTION PURSUANT TO FED. R. CIV. P. 56 FOR SUMMARY JUDGMENT OF PATENT INFRINGEMENT** with the Clerk of Court using CM/ECF which will send notification of such filing and we will hand deliver such filing to the following:

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Young Conway Stargatt & Taylor
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I hereby certify that on June 30, 2006, I have mailed via Federal Express, the document to the following non-registered participants:

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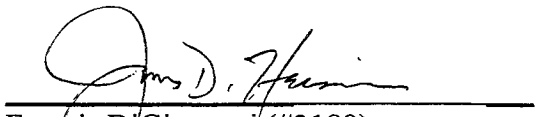

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED Defendants.	:	Civil Action No. 04-171-KAJ

ORDER

Whereas the Court, having considered the submissions and arguments of the parties,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED, that Glaxo Group Limited's Motion for Summary Judgment of Infringement of U.S. Patent No. 5,068,249 is GRANTED for the reasons set forth in Glaxo Group Limited's moving papers.

_____
United States District Court Judge